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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,935	10/12/2001	Donald E. Staunton	27866/36470A/US	1821

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MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,935

Applicant(s)

STAUNTON, DONALD E.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,18,19,22,24,25,30-32,36-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10-17,20,21,26-29,33-35 and 48 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/26/02, 12/9/02, 2/10/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. For the purpose of examination, the phrase "alpha/beta domain" is interpreted to mean a domain comprising alpha helix and beta sheet structures as discussed on page 1 of the specification.

Election/Restrictions

2. Applicant's election of the FtsZ species in the reply filed on 19 July 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 8, 9, 18, 19, 22, 24, 25, 30-32, 36-47, and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 19 July 2004. It is noted that the applicants election of the FtsZ species requires withdrawal of claims upon which the elected species do not read.

Specification

4. The disclosure is objected to because of the following informalities:
There is no brief description of the drawings.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the following reasons:

Several nucleotide sequences appear in the specification in figures 1 and 2 that are not properly identified. Nucleotide sequences must be identified by sequence identification number. Furthermore, if said sequences do not appear in the sequence listing, a new listing including said sequences must be supplied. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02). If said sequences consist of a portion of sequences already of record in the sequence listing, they may be identified in the specification using the existing SEQ ID No. accompanied by the position of the sequence on the already listed sequence.

Applicants are required to comply with all the requirements of 37 CFR §§ 1.821-1.825. Any response to this Office Action which fails to meet all of these requirements will be considered non-responsive. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

Appropriate correction is required.

Claim Objections

6. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 depends from itself.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-7, 10-17, 20, 21, 26-29, 33-35, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of contacting a protein containing alpha helices and beta sheet structures with an effector that interacts with an allosteric regulatory site of the protein and modulates binding of the protein with a ligand. In some embodiments the protein is broadly claimed as a molecule that is not LFA-1 or an I domain containing fragment thereof. In some embodiments the protein is more narrowly claimed as having less than 40% similarity to LFA-1. In some embodiments the protein is limited to the elected species of FtsZ and the ligand is GTP. In some embodiments the effector is a diaryl compound or a diaryl sulfide compound. In some embodiments the protein comprises a Rossmann fold with a 321456 beta sheet structure. In some embodiments the effector increases binding of the ligand and increases enzymatic activity of the protein. In some embodiments the effector decreases binding of the ligand and decreases enzymatic activity of the protein. It is emphasized that the generic claims are drawn broadly to all proteins that are not excluded. The claims read on both in vitro and in vivo methods.

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The specification describes in Table 1 on pages 30-66 lists 96 classes of proteins with alpha beta structures. The specification describes working examples of 9 proteins:

- 1) CD11B in example 3, pages 87-89 and example 16, pages 127-128
- 2 and 3) C2 and factor B in example 4, pages 89-96
- 4) alpha E beta 7 integrin in example 9, pages 107-111
- 5) alpha 2 integrin in example 11, pages 114-116
- 6) alpha 1 integrin in example 12, pages 116-122
- 7) Rac 1 in example 17, pages 128-131
- 8) ENR in example 21, pages 143-145
- 9) HPPK in example 19, pages 133-141.

In considering the broad scope of the generic claims the 9 species of proteins described do not adequately describe the generic claims. The broadest claim reads on methods utilizing all proteins that comprise alpha helix and beta sheet secondary structures except one protein, LFA-1. Description of methods using 9 proteins in the specification does not comprise a representative number of the undefined large genus of claimed methods.

Regarding the elected species of a method of using FtsZ, the specification shows in example 20 on pages 142-143 a prophetic example of a FtsZ binding assay, and describes FtsZ on page 19 and lists FtsZ in table 3 on page 84. However the specification does not describe an allosteric site in FtsZ, or effectors of any type of FtsZ. The specification does not describe the Rossmann fold structure of FtsZ. It is noted that claims 35 and 48 have been examined and not withdrawn although the specification does not show in Table 1 the elected species of protein FtsZ as required in claims 35 and 48. The specification does not describe a method utilizing FtsZ

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that comprises effectors, or the claimed structural limitations of FtsZ such as Rossmann folds, or the claimed structural and functional limitations of the effector such as increasing or decreasing binding or enzymatic activity and diaryl structures. In addition to the lack of description discussed in the preceding paragraph of the generic claims, the specification fails to describe the elected method.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 26-29 recite the limitation "the modulator" in claims 26 and 28. There is insufficient antecedent basis for this limitation in the claim.

The rejection would be overcome by amending the claims to recite the phrase "the effector."

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 4, 5, 7, 10, 13-17, 20, 21, 26, 27, 33-35, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (reference C59 in the Information Disclosure Statement filed 26 August 2002 as evidenced by Nogales et al. (reference C38 in the Information Disclosure Statement filed 26 August 2002)).

The claims are drawn to a method of contacting an FtsZ protein with an effector that interacts with an allosteric regulatory site and modulates binding of the protein with GTP. In some embodiments the protein comprises a Rossmann fold with a 321456 beta sheet structure. In some embodiments the effector increases binding of the ligand and increases enzymatic activity of the protein.

Yu et al. shows a binding assay in which Escherichia coli FtsZ protein is assayed for binding to GTP in figure 3 and pages 5457-5458. Yu et al. shows in figure 3 that calcium ions enhance binding activity of FtsZ and enhance GTPase activity of FtsZ. Yu et al. does not show inherent structural properties of FtsZ as in the instant claims.

Nogales et al. shows on page 451 that both tubulin and FtsZ have alpha helix and beta sheet secondary structures and comprise a beta sheet with 321456 structure.

Conclusion

14. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

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the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

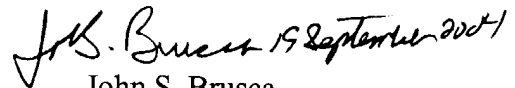
For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "John S. Brusca 19 September 2001".

John S. Brusca
Primary Examiner
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jsb